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BY FEDERAL EXPRESS

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket No. 2004-0324/CP1: AMENDMENT TO CITIZEN PETITION

Ladies/Gentlemen:

The undersigned Petitioner, Dey, L.P. ("Dey"), holder of New Drug Application ("NDA") 20-950 for the inhalation solution drug DuoNeb®, submits in quadruplicate this Amendment to the above-identified Citizen Petition filed 15 July 2004, pursuant to Section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §355(j)(5)(B)(iii), and FDA regulations §§ 21 C.F.R. §§ 314.95(a)(3), 10.20, 10.25 and 10.30.

1. Action Requested

Since the filing of its original Citizen Petition, Dey has learned that, contrary to its earlier understanding, the first ANDA applicant for a generic formulation of DuoNeb® to file a paragraph IV certification of invalidity or non-infringement against U.S. Patent No. 6,632,842 B2 assigned to Dey ("the 842 patent") appears to be Eon Labs, Inc., not Ivax Pharmaceuticals, Inc.

Accordingly, Dey hereby amends its original Citizen Petition to request written confirmation from FDA that Eon's ANDA 76-867 for a generic version of DuoNeb® is subject to a 30-month stay of final approval, based on the following analysis.

2. Statement of Grounds

a. The '842 patent issued on 13 October 2003, and was listed on 14 October 2003.

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b. Upon information and belief: (a) Ivax's ANDA was received by FDA on 22 April 2003; and (b) Ivax amended its ANDA to include a paragraph IV certification against the '842 patent on 09 December 2003.

c. Upon further information and belief, Eon's ANDA containing a paragraph IV certification against Dey's '842 patent was received by the FDA on 28 November 2003, 11 days earlier than the date Ivax filed its paragraph IV certification against this patent.

   Thus, contrary to what Dey had initially thought, Eon rather than Ivax appears to be eligible for 180-day exclusivity for generic DuoNeb®.*

d. Dey maintains that Eon's ANDA is subject to a 30-month stay of final approval, for the following reasons:

   - The new Hatch-Waxman 30-month stay provision that applies to ANDAs with Paragraph IV certifications against the '842 patent, 21 U.S.C. § 355(j)(5)(B)(iii) (as amended by Section 1101(a)(2)(A)(ii) of the Medicare Prescription Drug Improvement and Modernization Act of 2003), states in pertinent part:

     > "If the applicant made [a paragraph IV certification]...the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, *an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted...the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i)* or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action..." (emphasis supplied)

   Under this provision, a single 30-month stay of final approval will be accorded when a patent owner files an infringement action within 45 days after receiving notice of an ANDA applicant's Paragraph IV certification, if the patent is listed in the Orange Book before the ANDA is "submitted."

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* The other ANDA applicants for generic versions of DuoNeb® (Breathe Ltd., Alpharma, Inc. and Novex Pharma Division of Apotex, Inc.) all sent their paragraph IV notices to Dey after Eon did, and are therefore presumed to be subsequent paragraph IV filers to Eon.

- Upon information and belief: (i) Eon originally submitted its ANDA on 03 October 2004; (ii) the agency sent a "refuse to receive" letter to Eon on 19 November 2003 (a letter usually sent because of deficiencies in data or information in the application); (iii) Eon filed an amendment to its ANDA on 26 November 2003; and (iv) the ANDA was received for substantive review on 28 November 2003.

- As noted, the '842 patent was listed in the Orange Book on 14 October 2003.

- Dey commenced an action for infringement of the '842 patent on against Eon on 03 March 2004, within the 45-day period following 20 January 2004, the day Dey received Eon's written notice that Eon had filed an ANDA containing a paragraph IV certification against the '842 patent.

- Thus, Eon's ANDA was submitted approximately six (6) weeks after the '842 patent was listed in the Orange Book. Under amended Section 355(j)(5)(B(iii), Dey's filing of a patent infringement action within 45 days after receipt of Eon's notice letter, for a patent that was listed before Eon's ANDA containing a paragraph IV certification was filed, satisfies the requirements for a 30-month stay of final approval of Eon's ANDA.

- FDA regulations provide that an ANDA will be deemed received after the agency conducts an initial review to determine that it contains all necessary data and information to permit a substantive review. 21 C.F.R. § 314.101(b). While the new 30-month stay statute is silent on the definition of the term "submitted" in this context, Dey believes that the proper interpretation of "submitted" in the new 30-month stay statute is "received for substantive review" by FDA, since this is FDA practice under its regulations.

  Applying this interpretation, the date Eon's ANDA containing a Paragraph IV certification against the '842 patent was submitted was 28 November 2003, subsequent to the listing of the '842 patent on 14 October 2003 and thus subject to a 30-month stay of final approval under the language of the new statute.[**]

[**] If FDA were somehow to consider Eon's ANDA to have been "submitted" on 03 October 2003, the date Eon's ANDA was originally physically delivered to FDA, then Dey maintains that Eon's ANDA should still be subject to a 30-month stay of final approval, for the reason set forth in its original Citizen Petition filed in this docket, namely, Congress' intent that an ANDA is subject to at least one 30-month stay of final approval if a timely patent infringement action is commenced by a listed patent owner after receipt of notice of a paragraph IV certification.

In sum, in this amended Citizen Petition, Dey requests FDA's written confirmation that Eon's ANDA for generic DuoNeb® is subject to a 30-month stay of final approval.

3. Environmental Impact

Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.31.

4. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of this Citizen Petition.

5. Certification

The undersigned certifies that, to its best knowledge and belief, this Citizen Petition includes all information and views upon which the Petition relies, and includes representative data and information known to Petitioner which are unfavorable to the Petition.

Sincerely,

Michelle A Carpenter

Michelle A. Carpenter, J.D.
Vice President, Regulatory and Clinical Affairs

cc: Gary J. Buehler
Daniel E. Troy, Esq.